K003940

FEB - 8 2001

Zymed

Zymed Inc.
1201-B N. Rice Ave.
Oxnard, California 93030
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Fax 805.604.0493

510(k) Summary

Submitter:

Gretel Lumley, Quality Assurance Engineer
Zymed Medical Instrumentation
1201 B North Rice Avenue
Fax: 805-604-0493
Phone: 800-235-5941 (7417)
Date of Summary: 12-20-00
Contact: G. Lumley – see above

Trade Name: 2010 Plus Holter for Windows
Common Name: Holter Analyzer
Classification Name: Electrocardiograph, ambulatory, with analysis algorithm (per 21 CFR 870.2800)

Legally marketed device to which S.E. is claimed.
Zymed Holter Scanner Model Holter 2000 – 510(k) K990170
Zymed Holter Scanner Model 1610 – 510(k) K895208
Biosensor's Holter Monitor System – 510(k) K974192

Description: The 2010 Plus Holter for Windows is a device that analyzes recorded cardiac ECG and creates reports from the recorded data. The ECG is pre-recorded onto one of several data storage mediums, which is fed into the 2010 Plus Holter for Windows. The 2010 Plus Holter for Windows software analyzes the ECG and provides reports on a variety of cardiac data. The cardiac data that is analyzed is individual ECG waveforms and patterns of consecutive waveforms. Cardiac data provided by 2010 Plus Holter for Windows is used by trained medical personnel to diagnosis patients with various cardiac rhythm patterns.

The Zymed system presents the user with a number of clinical tools such as ECG report generation. The system also provides tools to review a patient's cardiac performance. Features such as individual ECG printouts, multi-channel automatic ST analysis, frequency domain Heart Rate Variability, multi-channel morphology analysis and Custom Reports further enhance the system's qualities as a valuable and practical clinical tool.

The system has the options available:
Full Arrhythmia analysis to include multi-channel automatic ST Analysis
12 lead ECGD
Data Acquisition on 2 or 3 Channels
Choice of Cassette Tape or Digital Input
Laser Printer

Indications for Use:

- Assessment of symptoms that may be related to rhythm disturbances of the heart in patients from pediatric to adult age. Patients with palpitations.

- Assessment of risk in Patients With or Without Symptoms of Arrhythmia. Patients with symptomatic or asymptomatic idiopathic hypertrophic cardiomyopathy and postmyocardial infarction patient with left ventricular dysfunction using arrhythmia e.g.: ventricular ectopy, as method of risk assessment.

- Assessment of efficacy of Antiarrhythmia Therapy. Patients with baseline high frequency, reproducible, sustained, symptomatic premature ventricular complexes supraventricular arrhythmia or ventricular tachycardia.

- Assessment of Pacemaker Function. Evaluation of patients with paroxysmal symptoms, detection of myopotential inhibition, detection of pacemaker mediated tachycardia, evaluation of antitachycardia pacing device function, evaluation of rate-responsive physiological pacing function.

- Detection of Myocardial Ischemia. Patients with chest pain suggestive of Prinzmetal's angina.

Review of Technology characteristics compared to the predicate device:

Specification/Feature	**Current Holter Holter Scanner Holter 2000**	**Modified Holter 2010 Plus Holter for Windows**
Platform:		
Type	IBM PC AT Compatible	Same
CPU	Pentium II 400 MHz Or greater	Same
RAM	128 Mbytes or greater	Same
Hard Disk	6 Gbytes or greater	Same
Floppy Disk	1.44 Mbytes	Same
Display	Direct Draw Capable, 1024 x 768 pixels, 16 bit Color	Same
Mouse	Yes	Same
USB	USB 1.2 or greater	Same
Software:		
Operating System	Windows 98, Windows NT	Same
Hardware and Software Diagnostics	Included	Same
Data Acquisition:		
Number of Channels	2 or 3	Same
Resolution	8 bit	Same

Sampling Frequency	192 samples per second	Same
Playback Speed	240 times real time	Same
Digital Input	Yes	Same

The only difference between the two Zymed systems is the addition of Frequency Domain Heart Rate Variability to the 2010 Plus for Windows System.

Overall Holter performance was measured against industry accepted AHA (AHA), MIT (MIT) and European ST-T (EST) databases. Results were typical for the Holter as targeted. Separate sensitivities (SE), positive predictivity (+P), and false positive rate (FPR) were examined for each database and measured for QRS, Ventricular, Couplets, Short runs and Long runs. Separate Episode Sensitivities (ESE), Episode Positive Predictivity (E+P), Duration Sensitivity (DSE) and Duration Positive Predictivity (D+P) were examined for the European ST-T (EST) database and measured for ST analysis. High heart rates to include pediatric patients were demonstrated to be within recommended guidelines in excess of 300 bpm, and performance in the presence of noise indicates the new system is equivalent to the old system when looking at baseline, electrode or muscle as the cause of noise.

In summary, performance data between the two systems were nearly identical, and therefore, supports a claim of Substantial Equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Gretel Lumley
Quality Assurance Engineer
Zymed Inc.
1201-B North Rice Avenue
Oxnard, CA 93030

Re: K003940
Trade Name: 2010 Plus Holter for Windows
Regulatory Class: II (two)
Product Code: MLO
Dated: January 26, 2001
Received: January 29, 2001

Dear Ms. Lumley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

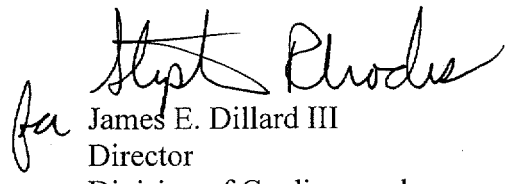
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you

might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number:

Device Name: 2010 Plus Holter for Windows

Indications for Use:

- Assessment of symptoms that may be related to rhythm disturbances of the heart in patients from pediatric to adult age. Patients with palpitations.

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003940

Prescription Use X or Over-The-Counter Use ____
(CFR21 CFR 801.109)